

Doing Business With ARPA-H

Industry Day

November 13, 2024

10:00 AM - 4:00 PM (ET)

Approved for Public Release: Distribution Unlimited



1. Why We're Here

Purpose and Expected Outcomes

Purpose:

Attend a virtual industry day event* centered on “Doing Business With ARPA-H”

Expected Outcomes

- Understand the sense of urgency for ARPA-H’s mission and focus areas
- Learn how ARPA-H applies unique R&D authorities to create flexible award instruments
- Identify how to locate and make submissions to current and future ARPA-H R&D opportunities
- Explore how ARPA-H is constantly improving its business processes
- Review ARPA-H’s solicitation instrument, including terminology and processes
- Obtain tips and lessons learned to assist with quality submissions



* Primary focus on the business aspects (not technical) of research and development (R&D) opportunities

Agenda - Main Session Topics

Topic #	Topic	Time (ET)
1	Why We're Here	10:00 - 10:10 AM
2	A Message From the ARPA-H Director	10:10 - 10:30 AM
3	A Message From the HHS Senior Procurement Executive	10:30 - 10:40 AM
4	Current Opportunities (GLIDE, CATALYST, OCULAB)	10:40 - 11:05 AM
BREAK		11:05 - 11:20 AM
5	Ways of Doing Business with ARPA-H	11:20 - 11:55 AM
6	Breakout Session 1 (see offerings on next slide)	11:55 AM - 12:30 PM
LUNCH BREAK		12:30 - 1:30 PM
7	Finding Opportunities	1:30 - 2:00 PM
8	Customer Experience Initiatives	2:00 - 2:20 PM
BREAK		2:20 - 2:35 PM
9	Innovative Solutions Opening (ISO) Process Overview	2:35 - 3:05 PM
10	Helpful ISO Resources	3:05 - 3:25 PM
11	Breakout Session 2 (see offerings on next slide)	3:25 - 4:00 PM

Agenda - Breakout Session Topics*

Topic #	Topic	Times (ET)
1	Work With Us Questions (Ask Me Anything)	Breakout Session Period 1: 11:55 AM - 12:30 PM Breakout Session Period 2: 3:25 - 4:00 PM
2	You Received an Award, Now What?	
3	Other Transaction (OT) Benefits	
4	Payable Milestones	
5	Intellectual Property (IP) Approach	
6	Teaming	
7	Affordability and Accessibility	
8	International Collaboration	
9	Accelerating Program Transition	
10	Engaging with Federally Funded Research and Development Centers and Government Entities	

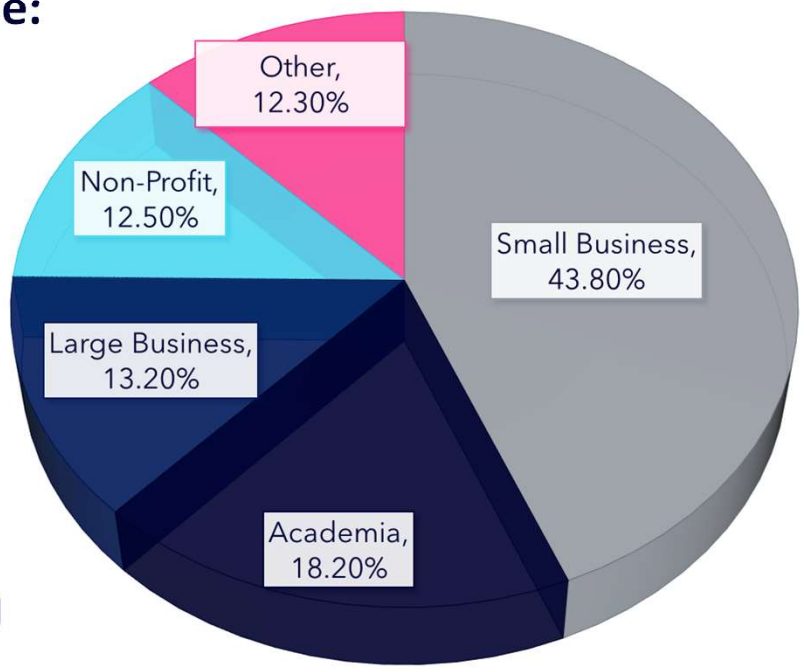
* All sessions are held at the same time per period



Registered Attendee Details

Total Registered: 1,916

Entity Type:



Preferred Topics (pre-event survey)

- Locating current/future opportunities*
- ARPA-H and its mission*
- Understanding ARPA-H authorities*
- Navigating ARPA-H's Solution Submission Portal*
- Other (breakout sessions)*

2. A Message from the ARPA-H Director

Mission

Accelerate better
health outcomes
for everyone.



ARPA-H Key Features and Authorities

ARPA-H has unique structures and legal authorities that allow it to **function like a business – quickly, nimbly, and decisively**

- ARPA-H is a **funding agency**
- **Independent** component of HHS
- No internal research labs; **disease agnostic**
- Generally, **fund outcome-based contracts**, not grants; accelerated award timelines
- Unique **FDA reimbursement authority**

FY 2022	FY 2023	FY 2024	FY 2025
\$1B	\$1.5B	\$1.5B	Request: \$1.5B




Lean and nimble management structure with autonomy in decision-making

ARPA-H Director **reports directly to HHS Secretary**



Term limits of 3-6 years bring urgency and idea flow

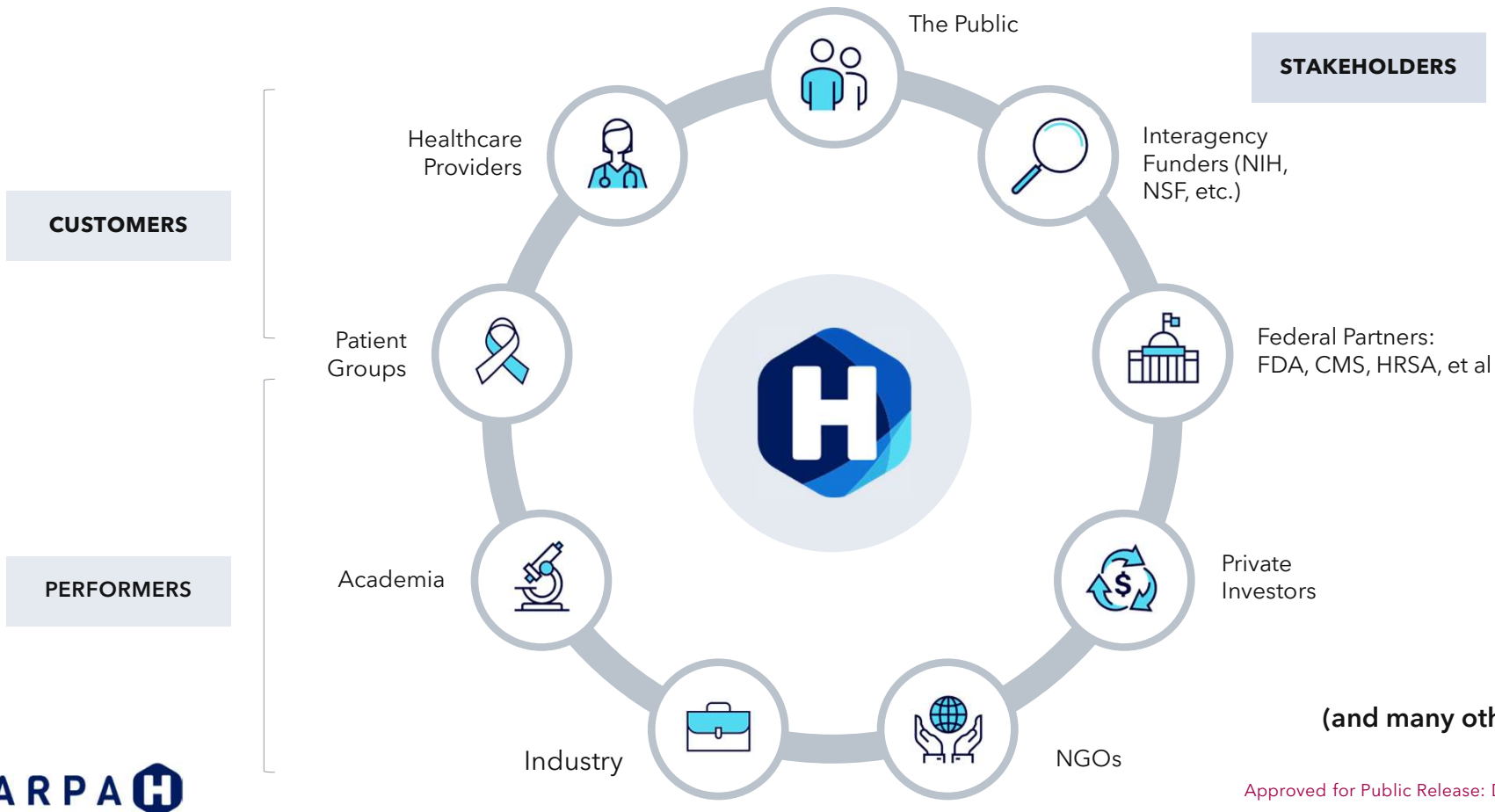
Flexibility in hiring allows ARPA-H to recruit at levels competitive with industry



Bottom-up decision-making. Program Managers have autonomy to make decisions quickly.

ARPA-H is a problems focused organization

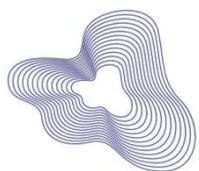
ARPA-H Accelerates the Entire Health Ecosystem



Mission Office Focus Areas

Further ARPA-H investment in these areas will generate asymmetrical benefits to the health ecosystem

Increasing the odds - at each step of the program lifecycle - that ARPA-H Solutions will transition to patients



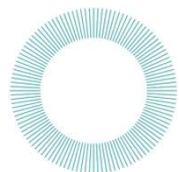
Health Science Futures (HSFO)

Expanding what's technically possible



Scalable Solutions (SSO)

Reaching everyone quickly



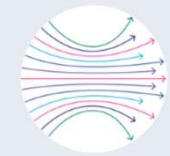
Proactive Health (PHO)

Keeping people from being patients



Resilient Systems (RSO)

Building integrated health care systems



Project Accelerator Transition Innovation (PATIO)

Ensuring programs and solutions transition, are commercialized, and are financially sustainable.



ARPANET-H

- Stakeholder and Ops
- Customer Experience
- Investor Catalyst



Program Lifecycle

From ideas to solutions in the real world



DESIGN PROGRAMS

- ARPA-Hard and well-defined problems in health
- Heilmeier framework
- High risk/High consequence
- Stakeholder Insights

BUILD A PERFORMER TEAM

- Solicit solutions from the community
- Find the best non-traditional, industry, and academics to solve
- Build new coalitions

EXECUTE & MEASURE

- Active program management against metrics
- Stakeholder engagement throughout to ensure transition
- Pivot resources when needed

LEARN & GROW

- Capture and share insights
- Technical honesty
- Advance the state of the art; 10x+ improvement, no incremental change

COMMERCIALIZE & TRANSITION

- Assist company formation or licensing
- Provide mentorship, connections to customers, investors
- De-risk investments


ARPA-H Timeline

Programs and Projects

ARPA-H appropriations passed in omnibus 12/23/2022

"Open for Business" ARPA-H launches its first Agency-wide Open BAA 3/15/2023

PROJECTS



CDTR CODA DARTS

HEART SPIKES THOR



REACT



ARPANET-H



PARADIGM



Women's Health



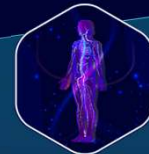
MATRIX



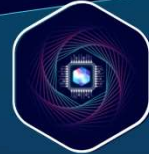
PIC-OCT



REO



LIGHT



PRECISE-AI



BREATHE



POSEIDON



EMBODY



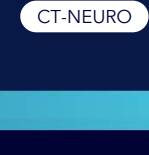
GLIDE



ADAPT



CT-NEURO



UPGRADE



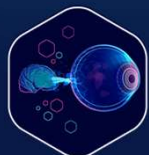
CUREIT



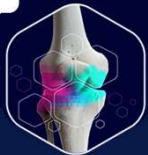
9 SBIRs



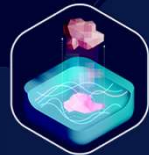
ACTR



THEA



NITRO



PSI



DIGIHEALS



BDF



APECx



HEROES

2022 2023

2024



ARPA-(H)eilmeier Questions

Towards a well-defined problem

- 1 What are you trying to do? What health problem are you trying to solve?
- 2 How does this get done at present? Who does it? What are the limitations of present approaches?
- 3 What is new about our approach? Why do we think we can be successful at this time?
- 4 Who cares? If we succeed, what difference will it make? What Health Outcomes are we accelerating?
- 5 What are the risks? That may prevent you from reaching your objectives? Any risks the program itself may present?

- 6 How long will the program take?
- 7 How much will the program cost?
- 8 What are our mid-term and final exams to check for success?
- 9 How will cost, accessibility, and user experience be considered to reach everyone?
- 10 How might this program be misperceived or misused (and how can we build trust and prevent that from happening)?



ARPANET-H: Hub & Spoke Network



ARPANET-H is a health innovation network that connects +500 members across a fragmented health ecosystem through projects, events, and collaboration opportunities.

Investor Catalyst Hub (located in Boston, MA):

Focused on navigating the complexities of the market landscape so innovations can transition from government support to commercial success.



Learn More

Customer Experience Hub (located in Dallas, TX):

Focused on engaging patients, providers, and stakeholders to bring them into the development and design process and enable faster, broader adoption of ARPA-H health innovations.



Learn More

Stakeholder and Operations Hub (located in Washington DC):

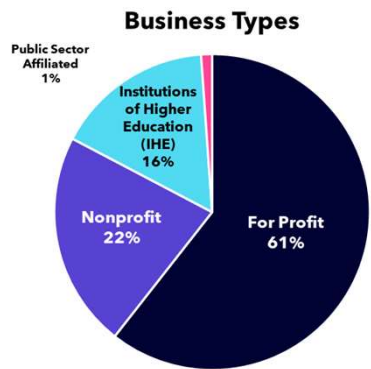
Focused on stakeholder engagements with our critical regulatory and legislative partners to support transitioning new health capabilities.



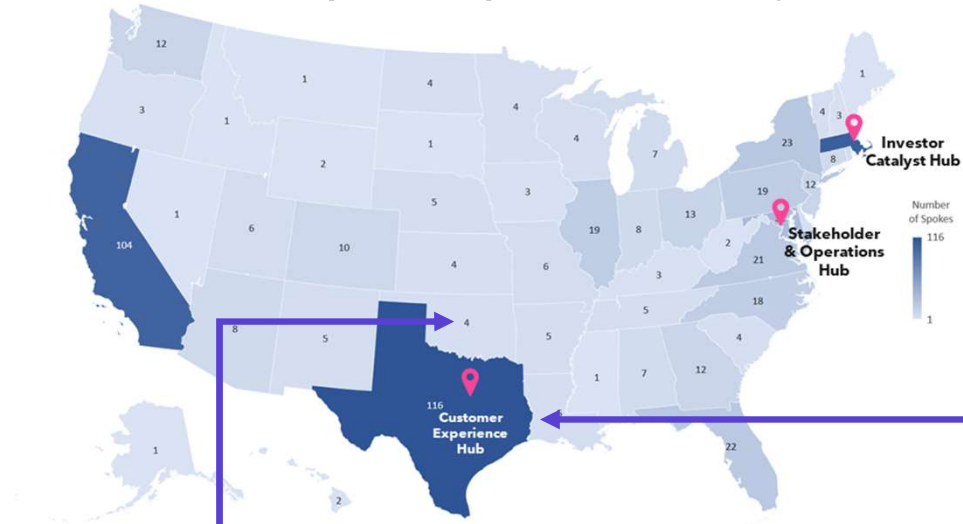
What if we had a national network of partners working to speed medical innovation to everyone?

ARPANET-H Network

Bridging disparate pieces of the health ecosystem & powering communities via ARPA-H



977 partners (spokes) and counting...



Spoke: The Engine



Customer Experience Hub

340+ small businesses (35%)
 185+ (19%) identify as:
 woman-owned,
 disadvantaged, service
 disabled and/or veteran-
 owned



Spoke: Cherokee Nation

ARPANET-H supporting our programs

Cherokee Nation was established as an ARPANET-H spoke through the Customer Experience Hub. This connection resulted in the NITRO program kicking off in the Cherokee Nation, the first R&D program to do so on Tribal Nation soil.



3. A Message from the HHS Senior Procurement Executive



Partnering with HHS

Enhancing the Health & Well-Being of the American Public

Ms. Katrina Brisbon
Department of Health and Human Services
Deputy Assistant Secretary for Acquisitions
Senior Procurement Executive

Doing Business with HHS



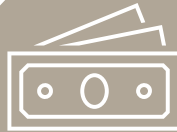
Mission

Evolving the Health &
Well-Being of the
American Public



Leveraging HHS Buying Power

Category
Management



Spend

How Does HHS
Spend and
What Does
HHS Buy

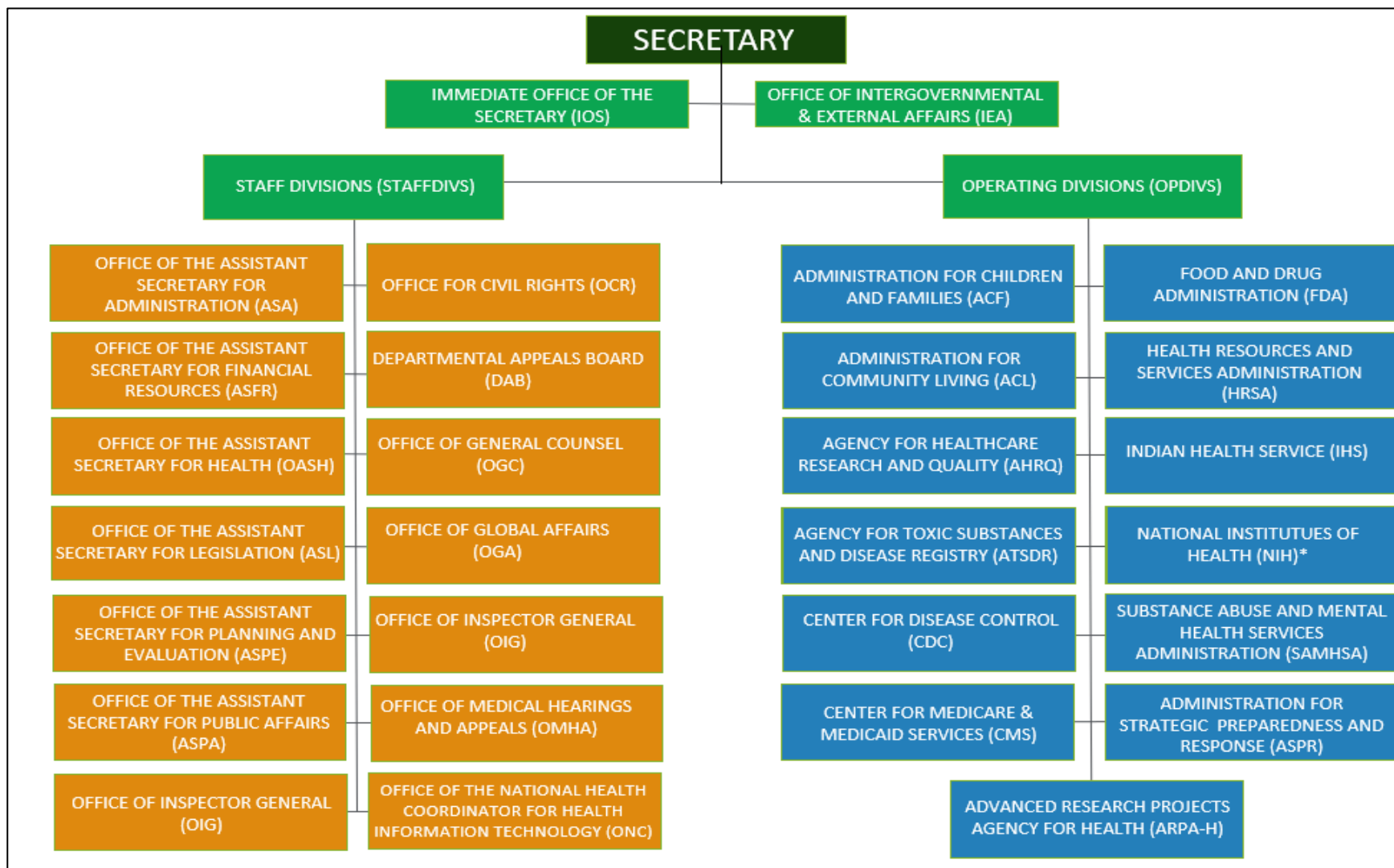


New Programs

Innovation and
Industry
Engagement

HHS MISSION

*The mission of the U.S. Department of Health and Human Services (HHS) is to **enhance the health and well-being of all Americans**, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.*



Highlighting HHS Mission Areas: Acquisitions Enables America's Health Care Programs



HHS's broad mission reaches into every aspect of American life, enhancing health & well-being from birth to life's end.

Center for Disease Control

Strengthening public health infrastructure to improve the overall health and resilience of communities.

Center for Medicare & Medicaid

Ensuring access to high-quality, affordable health care for all American

Food & Drug Administration

Ensuring safety of the nation's food supply & cosmetics

Indian Health Service

Ensuring access to equitable & comprehensive health services to Native communities

Health Resources and Services Administration

Improving health outcomes & achieving health equity for underserved, vulnerable, and geographically isolated populations

National Institutes of Health

Advancing knowledge & improving health through scientific discoveries that prevent disease & enhance treatment, resultantly improving public health globally

AHRQ

Improving patient safety, enhancing health care quality, and ensuring access to effective health services

ACL

Maximizing independence, well-being, & health of older adults and people with disabilities

ACF

Promoting self-sufficiency, child welfare, and equitable access to resources and opportunities for vulnerable populations.

Highlighting HHS Mission Areas: Acquisitions Enables America's Health Care Programs



HHS's broad mission reaches into every aspect of American life, enhancing health & well-being from birth to life's end.

ASPR

Strengthening the nation's health security & enhancing preparedness for public health emergencies.

ATSDR

Protecting communities from harmful health effects related to exposure to hazardous substances in the environment.

SAMSHA

Improving access to substance abuse prevention, treatment, and recovery services

ARPA-H

Driving transformative health innovations that support breakthroughs in medicine and health care



HHS FY24 SPEND BREAKDOWN BY OPERATING AND STAFF DIVISIONS

Level 1 GSA Taxonomy and FY24 spend by Operating and Staff Division. (Only includes obligations on FAR-based contracts)



Centers for Disease Control & Prevention



National Institutes of Health



Centers for Medicare & Medicaid Services



Assistant Secretary for Preparedness & Response



Administration for Children & Families



Food & Drug Administration

FY24 Total Spend	\$9.2B		\$8.0B		\$8.4B		\$6.3B		\$1.9B		\$1.7B	
Top 3 GSA Level I Categories ; Associated Spend (\$M)	1. Medical	\$7.0B	1. Professional Services	\$2.3B	1. Professional Services	\$4.6B	1. Research & Development	\$4.0B	1. Professional Services	\$1.7B	1. Information Technology	\$773.9M
	2. Professional Services	\$1.7B	2. Research & Development	\$2.2B	2. Information Technology	\$2.8B	2. Medical	\$1.7B	2. Information Technology	\$111.5M	2. Professional Services	\$662.6M
	3. Information Technology	\$743.5M	3. Information Technology	\$1.6B	3. Medical	\$655.8M	3. Professional Services	\$313.7M	3. Human Capital	\$63.6M	3. Industrial Products & Services	\$75.9M



Indian Health Service



Health Resources & Services Administration



Assistant Secretary for Administration



Substance Abuse & Mental Health Services Administration



Agency for Healthcare Research & Quality



Office of the Inspector General



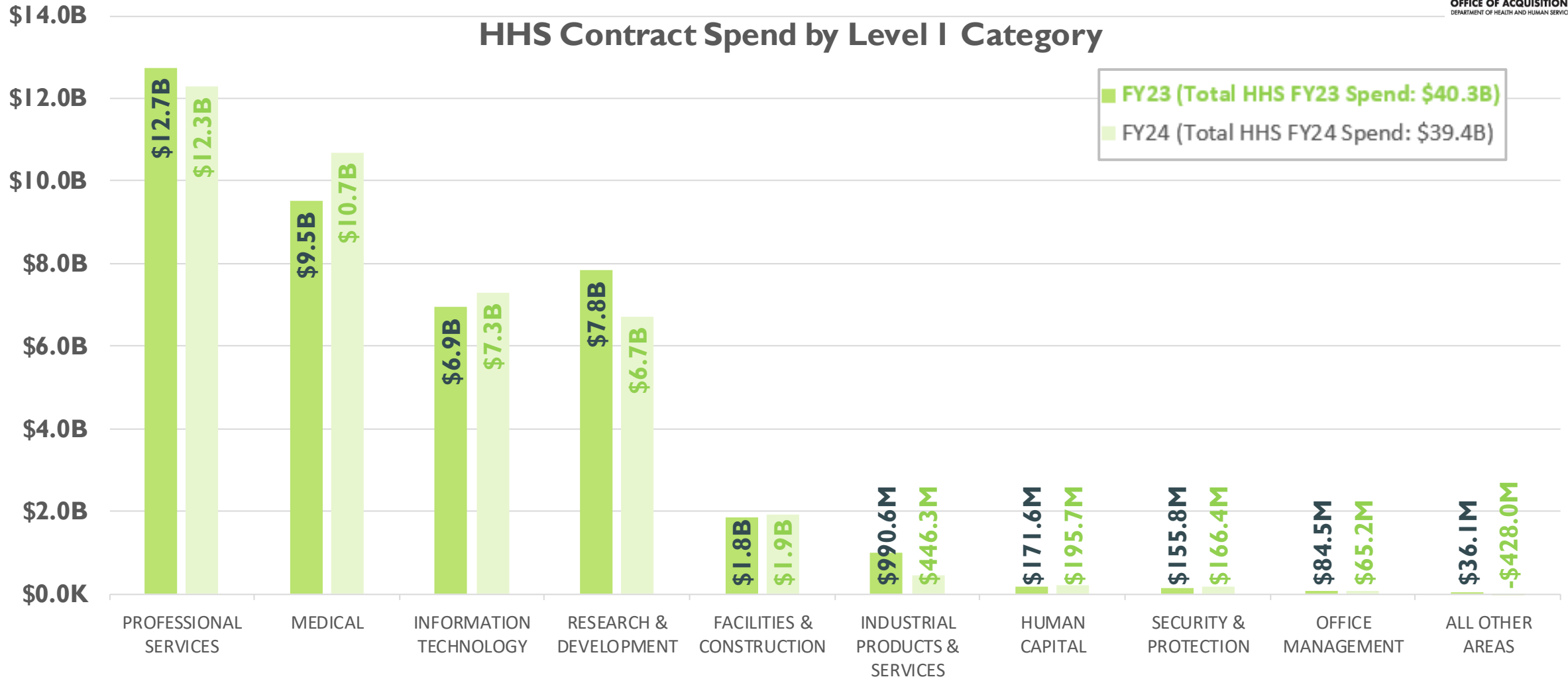
Advanced Research Projects Agency for Health

FY24 Total Spend	\$1.6B		\$578.2M		\$986.3M		\$345.3M		\$180.1M		\$94.3M		\$304.7M	
Top 3 GSA Level I Categories ; Associated Spend (\$M)	1. Medical	\$795.0M	1. Information Technology	\$295.2M	1. Information Technology	\$477.9M	1. Professional Services	\$307.1M	1. Professional Services	\$107.5M	1. Information Technology	\$61.1M	1. Research & Development	\$212.3M
	2. Facilities & Construction	\$347.0M	2. Professional Services	\$194.6M	2. Professional Services	\$327.8M	2. Information Technology	\$26.9M	2. Information Technology	\$38.1M	2. Professional Services	\$26.8M	2. Facility & Constructions	\$40.8M
	3. Information Technology	\$295.8M	3. Medical	\$67.1M	3. Medical	\$99.4M	3. Transportation & Logistics	\$8.8M	3. Research & Development	\$31.6M	3. Security & Protection	\$4.1M	3. Professional Services	\$39.6M

HHS Spend Comparison of FY23 and FY24 by Category



HHS Contract Spend by Level I Category



ARPA-H FY2024 OBLIGATIONS: OTHER TRANSACTION AGREEMENTS



OTHER TRANSACTION AGREEMENTS (OTAs)

TOTAL DOLLARS OBLIGATED: \$402.6M

TOTAL VALUE OF FY 2024 OTA AWARDS WITH OPTIONS: \$2.67B

Targeting the Market's Best for Health & Science

CATEGORY MANAGEMENT:

TARGETING THE FEDERAL MARKET'S BEST FOR HEALTH & SCIENCE

DEMAND MANAGEMENT PLAN

- Category Management Strategy
 - *Identifying optimal purchasing strategies for HHS mission needs and creating plans to increase efficiencies.*

STRATEGIC SOURCING

- Targeted “Mandatory Use” contracts to leverage the HHS purchasing power to find the best possible values & the right suppliers in the marketplace

PROGRAMS IMPACTING HHS INDUSTRY PARTNERS

New Programs



HHS Innovation Lab & Industry Liaison Program

Acquisition Innovation Lab

Driving value and supply chain optimization through continuous improvement and adaptation to changing market dynamics.

Industry Liaison Program

- Facilitating collaboration and communication
- Fostering mutually beneficial relationships through knowledge exchange research collaboration
- Facilitating the transfer of ideas and technologies



Fiscal Year 2024

13

HHS Procurement Organizations

68,355

Total Contract Actions

\$39,470,000,000

Annual Obligations on Contracts



OFFICE OF ACQUISITIONS
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. Current Opportunities

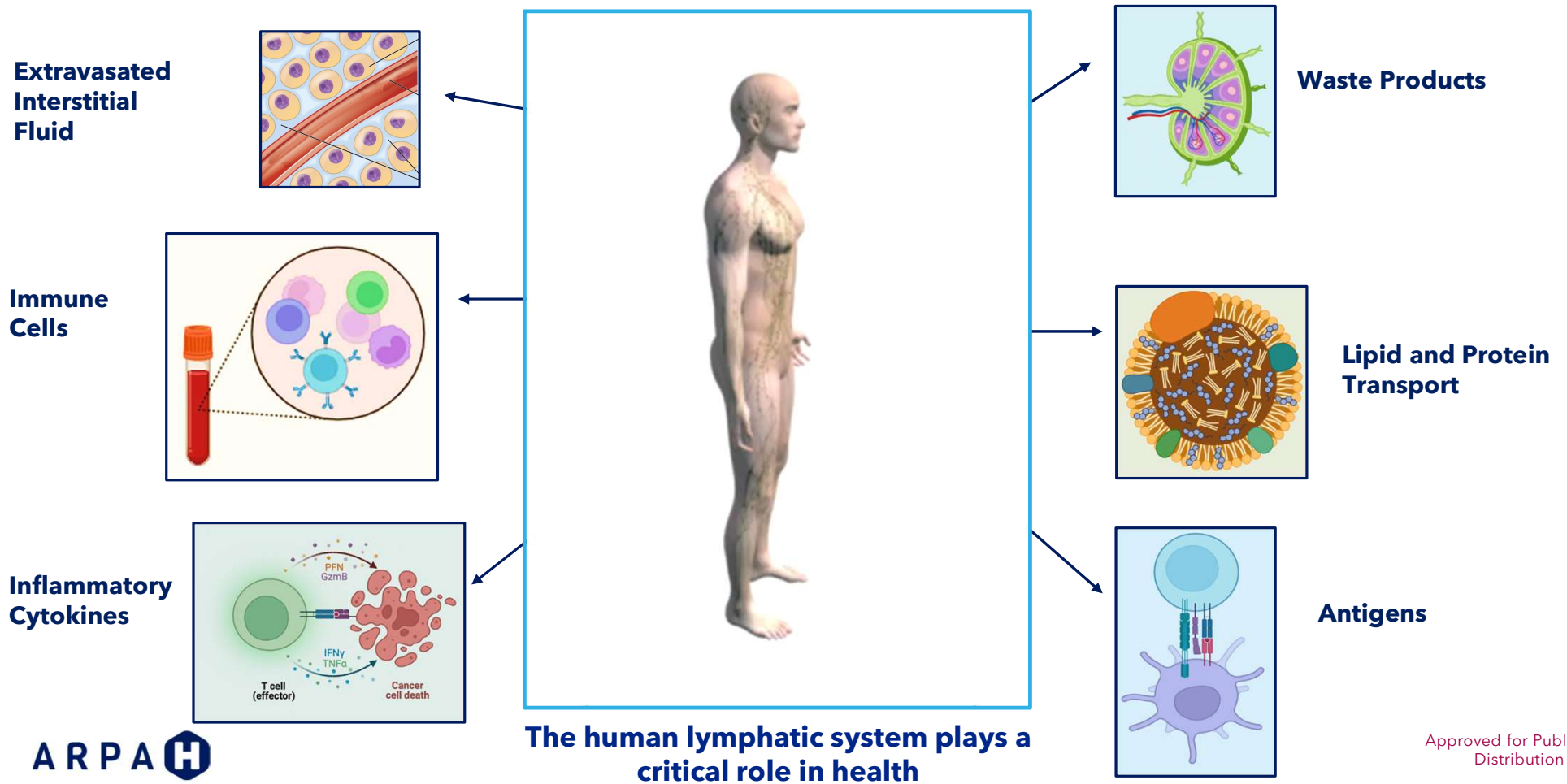


Lymphatic Portfolio

Kimberley Steele, MD, PhD

Program Manager, Health Science Futures Mission Office

The Human Lymphatic System In Health



Emerging Importance of Lymphatics in Health and Disease

CNS
 AD/Dementia/Aging
 CNS autoimmunity
 Cerebral small vessel disease
 Meningitis infection
 Hydrocephalous
 Traumatic brain injury

Lymphatic System
 Complex Lymphatic Anomalies:
 GLA, KLA, CCLA & GSD
 Castleman Disease
 Kaposi sarcoma
 Primary Lymphedema (40 + sub-categories)
 Vascular Anomalies

Eye
 Uveitis
 Glaucoma
 Corneal transplants
 Neovascularization
 Retinopathy
 Optic nerve pathology

Ear, Nose, Throat (ENT)
 Adenopathy (lymph node swelling)
 Meniere's disease

Cardiovascular System
 Myocardial infarction
 Heart failure
 Myocardial fibrosis
 Valvular disease
 Pericarditis
 Atherosclerosis
 Hypertension

Urologic System
 Kidney fibrosis
 Renal lymphangiectasia
 Nephrotic Syndrome
 Chronic cystitis
 Polycystic kidney disease
 Glomerulonephritis

Autoimmune Disorders
 Lupus
 Multiple sclerosis
 Sjogren's syndrome
 Rheumatoid arthritis
 Autoimmune inner ear disease

Pulmonary
 Pulmonary fibrosis
 Chronic obstructive sleep disorder
 Lymphangiomyomatosis (LAM)
 Pulmonary effusions
 Plastic bronchitis

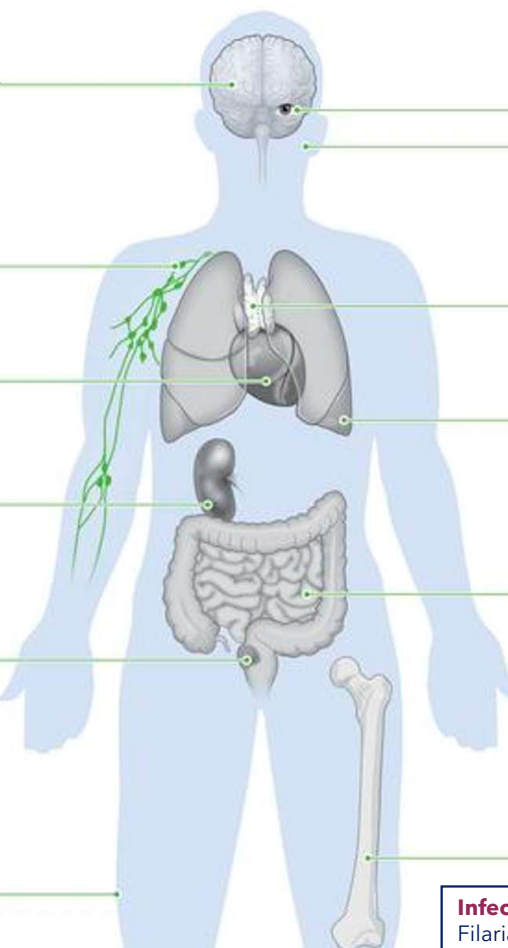
Tumor Metastasis
 Melanoma
 Gastrointestinal cancer
 Breast cancer
 Prostate cancer
 Testicular cancer
 Squamous cell cancer
 Gynecological cancers (endometrial, ovarian)
 Colorectal cancer
 Lung cancer

Skin
 Lymphedema
 Lipedema
 Lymphangitis
 Scleroderma
 Atopic Dermatitis
 Eczema
 Aging
 Hair follicle
 Stem cell maintenance

GI System
 Inflammatory bowel disease
 Celiac disease
 Intestinal lymphangiectasia
 Diabetes
 Obesity
 Chylous ascites
 Liver fibrosis / cirrhosis
 Fatty liver disease
 Hypercholesterolemia
 Protein-Losing Enteropathy (PLE)

Musculoskeletal System
 Osteoarthritis
 Psoriatic arthritis
 Fibromyalgia
 Gorham-Stout disease

Infection
 Filariasis
 HIV, COVID, Tuberculosis
 Meningitis



Adapted from: J Clin Invest DOI: 10.1172/JCI171582



We have diagnostic and therapeutic tools to assess and treat all our body systems... except our lymphatic system.



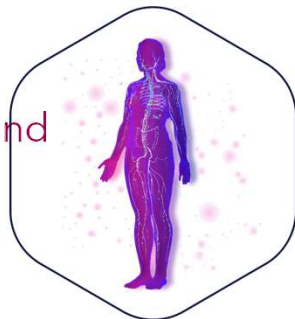
So, why not LYMPHATICS ?

Because we would need to MAKE THE INVISIBLE VISIBLE and it is a HARD problem to solve.

But if we could, we might be able to save millions of lives.

LIGHT

Lymphatic Imaging, Genomic, and Phenotyping Technologies



Vision: Create a diagnostic toolkit that is scalable, accessible, accurate, and clinically useful to detect lymphatic structure and function in health and disease.

Technology Focus Areas

- TA1. Diagnosis and monitoring through biomarker discovery
- TA2. Imaging technologies
- TA3. Prevention, prediction, and diagnostic confirmation through genetics, epigenetics, and models of lymphatic dysfunction

What if we could make the invisible lymphatic system visible?



GLIDE

Groundbreaking Lymphatic Interventions and Drug Exploration



22

Vision: To develop treatment options that address the underlying mechanisms of lymphatic dysfunction; either curing the disease state or safely stabilizing the disease and providing significant relief.

Technology Focus Areas

- TA1. Restore Flow Through Physical Interventions
- TA2. Normalize Function Through Targeted Pharmacologic, Gene & Cell Therapy

What if doctors were able to prevent and cure human disease by targeting the lymphatic system?

Approved for Public Release: Distribution Unlimited

ARPA-H Lymphatic Portfolio Interest Areas

Lymphatic Health Interests*	Sprint for Women's Health	LIGHT Program	GLIDE Program	SBIR Topic LymphoLab Toolkit	SBIR Topic Ambulatory Edema Monitor
Meningeal Lymphatics, Glymphatic & CNS	○		○		
Lymphatic System-wide		○	○	○	○
Rare & Chronic Disease Required			○		
Multiple Indications Required			○	○	○
Diagnostics	○	○			○
Imaging Development	○ brain lymphatics only	○ whole body, excludes brain			
Biomarker Discovery		○		○	
Genomics Characterization		○		○	
Physical Intervention	○		○		
Targeted Therapeutics	○		○	○	
Gender Specificity	○				
First-in-Human Demonstrations		○	○		○
Addressing Barriers of Lymphatic Diagnosis & Treatment	○	○	○	○	○

*Represents interest areas only and does not reflect what has or will be selected for negotiation



GLIDE

into the future with...

Groundbreaking Lymphatic Interventions and Drug Exploration



24



**Solution Summary deadline:
12/02/24**

QR Code links to:

- GLIDE Overview
- Proposer's Day Recording
- GLIDE Solicitation
- FAQs
- Teaming Profiles

Computational ADME-Tox and Physiology Analysis for Safer Therapeutics (CATALYST)

Dr. Andy Kilianski, Program Manager
Health Science Futures Mission Office

Vision: To revolutionize preclinical drug safety prediction by developing human-based models that accurately estimate toxicity and safety profiles for drug candidates. If successful, CATALYST will enable safer and faster drug development, particularly for rare disease populations.

Technology Focus Areas

- Data discovery and deep learning methods for drug safety models
- Living systems tools for model development
- In silico models of human physiology

Key Dates

- Program Launch: October 4, 2024
- Program ISO Released: October 16, 2024
- Proposers' Day: October 29, 2024
- Solution Summary Due: November 25, 2024, 5:00 p.m. ET



Approved for Public Release: Distribution Unlimited



What if we could predict drug safety and efficacy accurately before clinical trials even begin?

Ocular Laboratory for Analysis of Biomarkers (OCULAB)

Dr. Calvin Roberts, Program Manager
Health Science Futures Mission Office

Vision: To revolutionize how we think about continuous health monitoring and disease detection with a first disease target of dry eye disease (DED).

Technology Focus Areas

- Development of a continuous monitoring nanosensor for the tear duct
- Development of closed-loop therapeutic dosing device

Key Dates

- Program Launch: October 18, 2024
- Program ISO Released: TBD
- Proposers' Day: December 12, 2024
- Solution Summary Due: TBD



Approved for Public Release: Distribution Unlimited



**What if your eyes were a
window to your health?**

5. Ways of Doing Business With ARPA-H

Contracting Instruments (Per 42 U.S.C. 290c)

Other Transactions (OTs)

Cooperative Agreements (CAs)

**Focus of today's event
(research and development,
or R&D, efforts)**

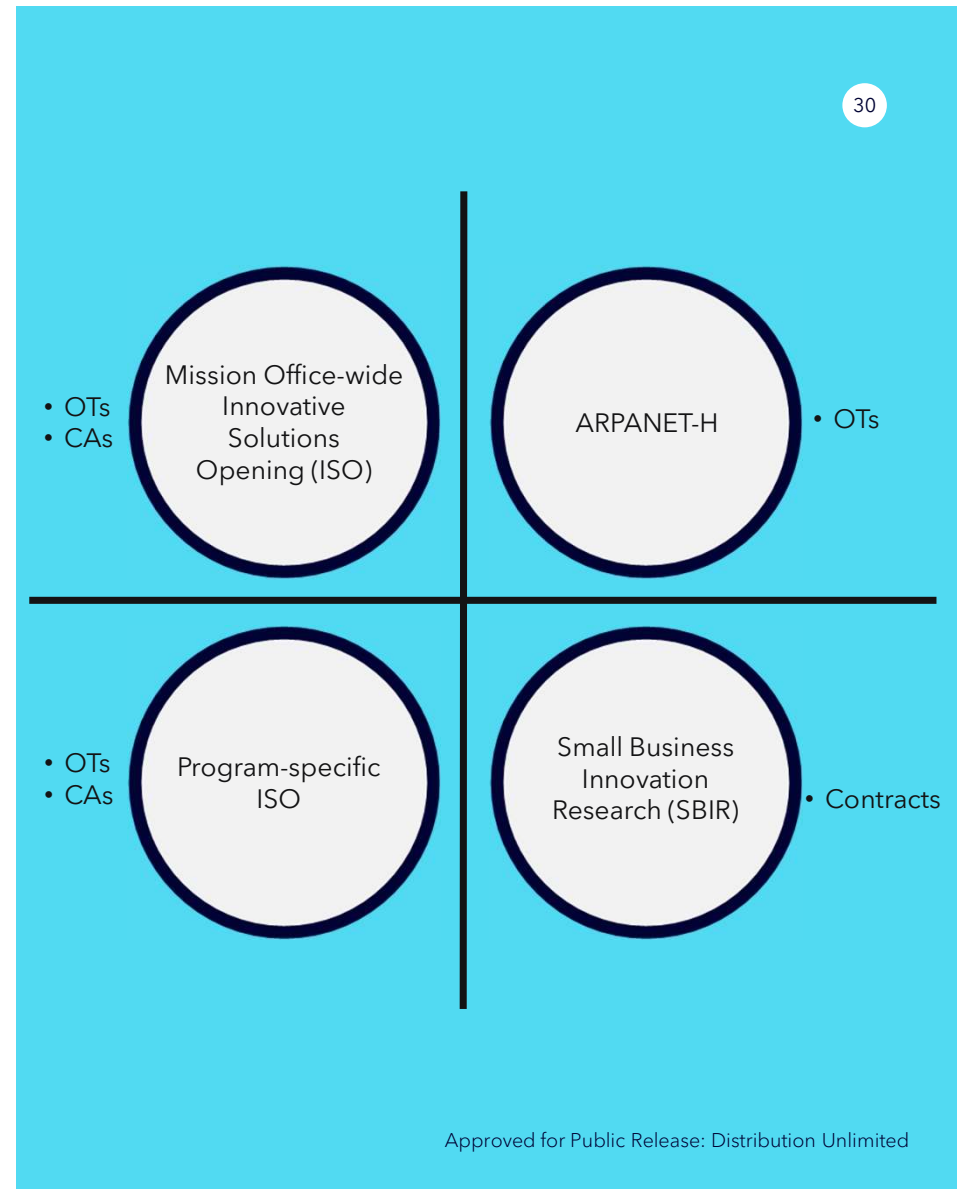
Contracts

Grants

Prizes

Potential Award Types Per Activity

- Will primarily use OTs and CAs for R&D efforts
- Will discuss ISOs and ARPANET-H more in main session and breakout sessions



Other Transactions (OTs)

Definition

Legally binding agreements (other than procurement contracts, grants, or cooperative agreements) between industry and the Gov't to conduct research and development efforts and promote innovation to achieve its goals.



When to Use

A project that requires creative relationships and practices with solutions providers, especially those that may not be interested in entering FAR-based contracts or federal financial assistance.

When the government requires innovative and flexible arrangements via a highly-collaborative environment with solutions providers.

A project that requires the use of a contract vehicle with characteristics similar to those within the commercial industry.

OT Advantages / Disadvantages



Advantages

- The most flexible authority when compared to contracts, cooperative agreements, and grants
- Instrument characteristics are similar to contracts within the commercial sector
- Processes based on negotiations rather than regulations/policies
- Bayh-Dole Act (Intellectual Property) does not apply → more flexibility
- Does not require excessive oversight or specialized accounting/audit requirements and systems



Disadvantages

- Some industry partners, primarily academic institutions, may not have experience with OTs
- Does not guarantee ARPA-H teams to complete awards faster than contracts, cooperative agreements, or grants

Cooperative Agreements (CAs)

Definition

A legal instrument (federal financial assistance) between a Federal awarding agency and a recipient or a pass-through entity and a subrecipient that:

- 1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value to carry out a public purpose authorized by a law of the US (and not to acquire property or services for the Federal Gov't or pass-through entity's direct benefit or use).
- 2) Provides for substantial involvement of the Federal awarding agency in carrying out the activity contemplated by the Federal award.



When to Use

A project that requires recipients to receive approval in a program activity stage before starting work on a subsequent stage.

When the government must provide specific direction or redirection of the work.

A project that necessitates government monitoring of recipient work to ensure compliance with requirements (beyond what's considered normal programmatic monitoring or stewardship).

CA Advantages / Disadvantages



Advantages

- Academic institutions and non-profits are familiar and comfortable with cooperative agreements (most have business practices and systems already set-up)
- May permit flexibilities including allowing up to 90-day pre-award cost, carryover of unobligated (unexpended) funds from one budget period to the next, and initiation by the recipient of a one-time extension of the PoP by up to 12 months
- Rebudgeting among direct cost categories where the transfer of funds does not exceed 10% or more of total costs of the most recently approved award
- Does not require HHS leadership pre-award approval



Disadvantages

- Mainly geared towards academic institutions (colleges and universities) and intended for early stage/basic research
- Not appropriate for acquiring prototypes - deliverables are generally reports only
- No exceptions to Bayh-Dole Act (Intellectual Property) → less flexibility
- Processes based on regulations/policies rather than negotiations
- Does not allow for the payment of profit or fee (exception under HHS policy allows for the profit/fee on SBIR/STTR grants)

Innovative Solutions Opening (ISO) Overview

- ARPA-H’s preferred solicitation instrument for R&D efforts (programs and projects)
 - Created by ARPA-H (unique to ARPA-H’s needs/mission)
 - A competitive process with award decisions focused on technical quality (best ideas > best price)
 - Submissions reviewed/evaluated on their merit (not compared with other submissions)
 - Does not originate from the Federal Acquisition Regulation (FAR) → provides more flexibility than Broad Agency Announcements (BAAs)
- Replaced the “Open Office BAA” used from March 2023 to March 2024
 - ARPA-H does not plan to use BAAs in the future
- ISO types:
 - Program-Specific ISOs (highest ARPA-H priority)
 - Mission Office ISOs



Proposer Eligibility

- Any entity capable of satisfying the government’s needs may complete a submission to an ARPA-H ISO (i.e., small businesses, large businesses, nonprofit research institutions, and academia to include Minority Serving Institutions)
- Potential prohibitions and limitations:
 - Federally Funded Research and Development Centers (FFRDC)*
 - Other government entities*
 - Federal government employees*
 - Non-US entities*
 - Concurrent award count (no more than three) → See individual solicitation language

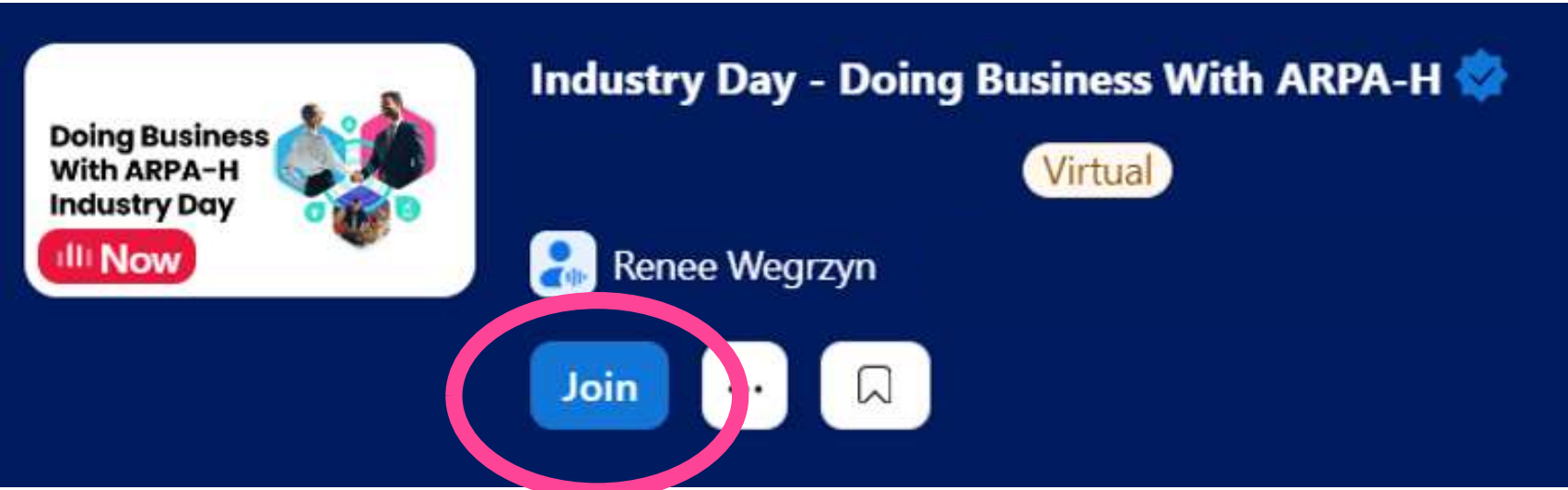
* Breakout sessions are available to provide more information on these topics



6. Breakout Period 1

Logistics for Breakout Rooms

- Join one of the 10 breakout sessions offered ("Session 1")
- The breakout session period is 35 minutes
- Ask questions in the chat
- All will rejoin main session room at 1:30PM (after lunch break)



Breakout Session Topics and Descriptions

Topic #	Topic	Description
1	Work With Us Q&A	Ask questions related to doing business with ARPA-H (“Ask Us Anything”)
2	You Received an Award, Now What?	An overview of typical post-award activities associated with ARPA-H research and development (R&D) efforts
3	OT Benefits	An overview of OTs and the expected benefits of using OTs
4	Payable Milestones	An overview of ARPA-H’s preference for payable milestones on R&D efforts
5	Intellectual Property (IP) Approach	An overview of IP and ARPA-H’s approach to IP
6	Teaming	An overview of teaming opportunities within specific ARPA-H programs and the importance of teaming with small business and Minority Serving Institutions (MSIs)
7	Affordability and Accessibility	An overview of affordability and accessibility and the importance to ARPA-H’s mission
8	International Collaboration	A session on opportunities for international collaboration, for both domestic and foreign proposers
9	Accelerating Program Transition	An overview of PATIO and the goal to transition health research innovations into solutions that reach everyone
10	Engaging with FFRDCs and GEs	Learn how ARPA-H can collaborate with FFRDCs and government entities

7. Finding Opportunities

How to Find Opportunities - Overview

- **Online:** ARPA-H.gov
- **Email:** Vitals Newsletter
- **Social Media:** ARPA-H accounts
- **SAM.gov:** Search function



How to Find Opportunities - Online

Online: ARPA-H.gov

Open Funding Opportunities Page

Provides a list of all currently open ARPA-H funding opportunities, including Program-Specific ISOs, Mission Office ISOs, Small Business Awards, and Research Sprints.

arpa-h.gov/engage-and-transition/open-funding-opportunities

Programs Page

Provides a list of all ARPA-H programs, including those with active solicitations and those that are closed.

arpa-h.gov/research-and-funding/programs

Mission Office ISOs Page

Provides links to the Innovative Solutions Openings for each of the 4 ARPA-H Mission Offices: Health Science Futures, Resilient Systems, Proactive Health, and Scalable Solutions.

arpa-h.gov/research-and-funding/mission-office-iso



How to Find Opportunities - Email

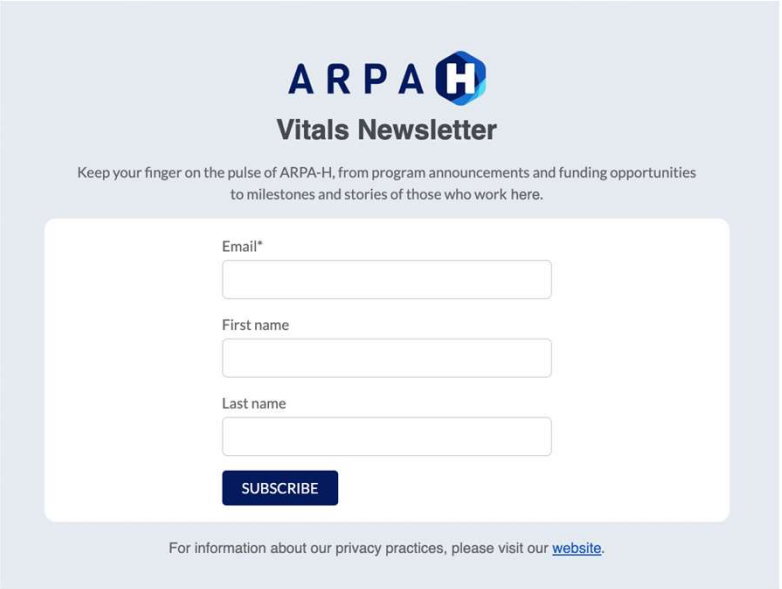
Email: Vitals Newsletter

Sign up on ARPA-H.gov

Provides bi-weekly updates about ARPA-H research opportunities and news direct to your email

Sign up using the footer bar of arpa-h.gov or visit the Vitals Newsletter sign up page:

engage.arpa-h.gov/arpa-h-vitals-newsletter-sign-up



The screenshot shows the ARPA-H Vitals Newsletter sign-up page. At the top, the ARPA-H logo is displayed above the text "Vitals Newsletter". Below this, a short paragraph reads: "Keep your finger on the pulse of ARPA-H, from program announcements and funding opportunities to milestones and stories of those who work here." The main form area contains three input fields: "Email*" (required), "First name", and "Last name". A dark blue "SUBSCRIBE" button is positioned below the last name field. At the bottom of the form, a small link reads: "For information about our privacy practices, please visit our [website](#)."



The footer bar features a white rounded input field with the placeholder text "Enter email to subscribe (required)" and a blue rounded "Sign up" button.

How to Find Opportunities - Social Media/SAM.gov

Social Media: ARPA-H accounts

Follow on ARPA-H.gov

Provides regular updates about ARPA-H research opportunities and news through a variety of channels:

- **LinkedIn:** [ARPA-H](#)
- **Instagram:** [@ARPAHealth](#)
- **X/Twitter:** [@ARPA_H](#) and [@ARPA_HDirector](#)
- **YouTube:** [@ARPA-H](#)

Content tagging ARPA-H is viewed for potential amplification by the social media team.

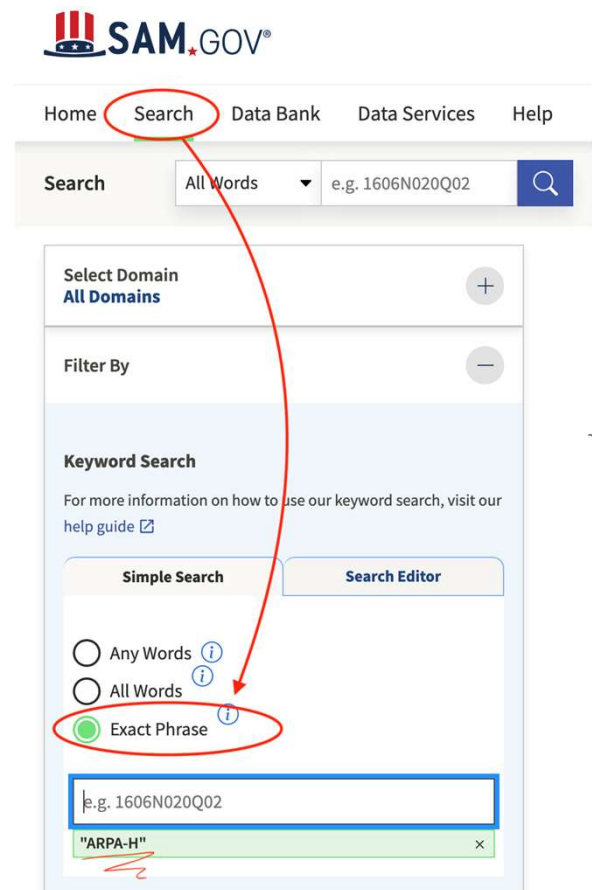


How to Find Opportunities - Social Media/SAM.gov

SAM.gov:

Search the exact phrase "ARPA-H"

- Provides an official government list of all ARPA-H funding awards both past and present
- Open [SAM.gov](https://sam.gov) search function, select "Exact Phrase," and enter "ARPA-H"



Live Demonstrations

- **ARPA-H Website**
 - Open funding opportunities
 - Submission Resources and FAQs
 - Vitals newsletter
- **Social media**



8. Customer Experience Initiatives

Customer Experience Initiatives - ARPA-H Website

Resources Page

- Funding awards process
- Common terms and definitions
- Sample forms and templates
- Frequently Asked Questions
- arpa-h.gov/engage-and-transition/submission-resources-and-faqs

UI/UX Redesign

- Improved navigation
- In-depth user testing
- Better data analytics
- New components and capabilities
- Design facelift



Customer Experience Initiatives - OT Community

- In July 2024, ARPA-H launched the OT Community
- Free for the public to access content at ARPA-H.gov
- Why?
 - Broadly speaking, OT authority is misunderstood across the federal government and is not being utilized to the greatest extent
 - There are limited OT-related resources (including training products) available to personnel within the federal government and industry
- Expected Benefits?
 - A community focused on OTs with active collaboration (i.e., training, mission assistance)
 - Timely access to relevant OT resources and information

<https://arpa-h.gov/engage-and-transition/other-transaction-community>



Customer Experience Initiatives - ISO Process

- Health and Human Services (HHS) launched a large initiative in October 2023 involving many HHS Operating Divisions to enhance the customer experience relative to new or existing projects
- ARPA-H selected “the ISO process” for its project
 - Obtained feedback from internal subject matter experts and external submitters to initial ISOs
 - Conducted user testing of the ISO submission process through ARPA-H’s Solution Submission Portal
- ARPA-H updated its website, enhanced its submission portal, and changed business processes to enhance the customer experience for ISOs
- ARPA-H will remain flexible and constantly adjust based on performer feedback to operate with the most efficient and effective business processes

Customer Experience Initiatives - Performer Feedback

- ARPA-H is a bold and unique organization that plans to experiment with business processes to maintain efficient/effective business processes and keep barriers to entry low
- ARPA-H desires feedback from performers associated with R&D projects
- Performers may submit constructive feedback to DBWA@arpa-h.gov at any time during the performance period

9. Innovative Solutions Opening (ISO) Process Overview

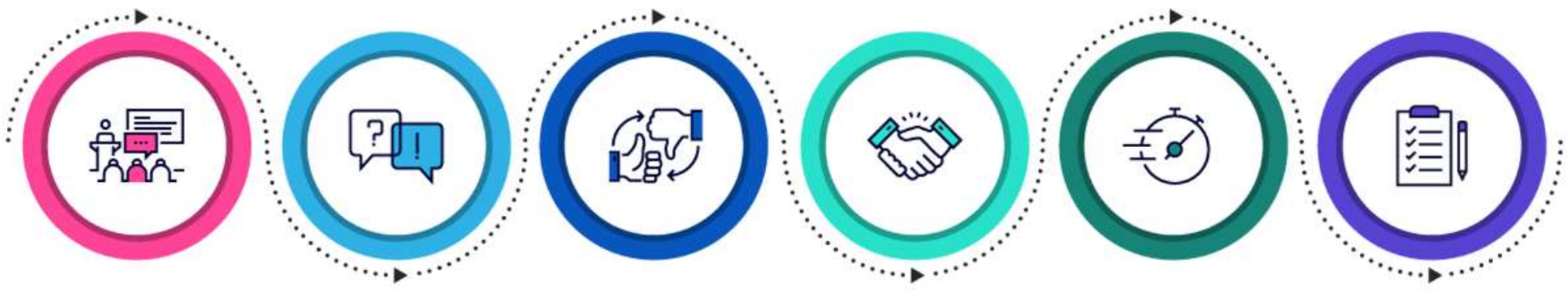
ISO-Related Terms and Definitions

Term	Definition
ISO	ARPA-H's unique solicitation instrument, which can either be in the form of a Program-Specific or Mission Office ISO
Program-Specific ISO	Used to solicit potential solutions for a specific ARPA-H program
Mission Office ISO	Used to solicit potential solutions that fall within a mission office area of research interest but may not be addressed by any specific ARPA-H program
Solution Summary	A concept summary document with minimal pages for proposers to submit to ARPA-H prior to investing resources for a full proposal submission
Full Proposal	A full application for a new or innovative idea
Pitch Presentations	A type of oral presentation that may be required of proposers (as an element of proposal evaluations)

ISO-Related Terms and Definitions (cont.)

Term	Definition
Encourage / Discourage	Potential feedback options from ARPA-H for solution summaries
Selected / Not Selected	Potential feedback options from ARPA-H for proposals
Non-conforming	Potential feedback option from ARPA-H for submissions that do not follow ISO instructions for proposals
Solution Submission Portal	ARPA-H website for solution summary and proposal submissions in response to active ISOs (registration required)
Other Transaction	An R&D award vehicle governed by 42 U.S.C. 290c(g)(1)(D)
Cooperative Agreement	A type of federal financial assistance instrument to transfer something of value to carry out a public purpose and not to acquire property or services (substantial involvement by ARPA-H is expected)

General Process Overview (for R&D efforts)



Planning and Initiation

ARPA-H identifies a broad research focus area or launches a specific research program

Solicitation

ARPA-H releases solicitations, usually in the form of an Innovative Solutions Opening (ISO)

Evaluation and Selection

Proposers submit solution summaries or full proposals and ARPA-H provides feedback

Negotiation and Award(s)

ARPA-H makes awards to submitter(s) after negotiating terms and conditions

Performance

Performers execute tasks and receive payment per agreement milestones and payment terms

Completion and Closeout

When the research is done, ARPA-H closes the agreement but provides ongoing product support



Program-Specific ISOs

- Used for most ARPA-H programs
- Draft ISO may be published until approved ISO is available
- Usually open for about 60 days (for solution summary submissions)
- Proposers' Day event likely (in-person and/or virtual)
 - Share information on the program and ISO process
 - Encourage team networking
- Programs usually involve phases over multiple years
- Multiple awards expected (OTs and/or CAs)
- Q&A about the program is usually available on ARPA-H's website and SAM.gov
- Generally include technical areas, objectives, phases, go/no-go phase checkpoints, and metrics

Program-Specific ISOs (cont.)

- A solution summary may be required prior to proposal submission
- Pitch presentations may be utilized as a part of the evaluation process
- Typical evaluation criteria*:
 - Overall scientific and technical merit
 - Proposer’s capabilities and/or related experience
 - Potential contribution and relevance to the ARPA-H mission
 - Price analysis
- Usually include format and instructions for required submission contents
- No reimbursement for solution summary submissions, proposal submissions, or Proposers’ Day attendance

* Order of evaluation criteria importance can vary by ISO



Mission Office ISOs

- One for each MO (“office-wide”)
 - Resilient Systems Office (ARPA-H-SOL-24-103)
 - Health Science Futures (ARPA-H-SOL-24-104)
 - Scalable Solutions (ARPA-H-SOL-24-105)
 - Proactive Health Office (ARPA-H-SOL-24-106)
- Usually open for multiple years (can be adjusted or renewed)
- Multiple awards expected (OTs and CAs)
- Solution summary required before proposal submission
- No reimbursement for solution summary or proposal submissions

Mission Office ISOs (cont.)

- ARPA-H intends to review solution summaries and provide feedback within 30 business days of solution summary receipt
- If encouraged for proposal submission, proposers will have 45 days to complete the submission
- Typical evaluation criteria:
 - Overall scientific and technical merit
 - Potential contribution and relevance to the ARPA-H mission
 - Proposers' capabilities and/or related experience
 - Cost realism
- ARPA-H intends to review proposals and respond to proposers within 60 days of proposal receipt

Conforming Proposals*

- Proposed concept applies to mission office interest area(s)
- Proposer meets eligibility requirements
- Proposal meets submission requirements
- Proposal meets content (attachments) and formatting requirements
- Proposer's concept not already funded (or selected for award negotiations) for another funding opportunity with ARPA-H or another government entity

* Non-conforming proposals may be removed from consideration (proposers will be notified via email)



Submitting on ARPA-H's Solution Submission Portal

1. Sign up for an account at <https://solutions.arpa-h.gov> (if you don't already have one)
2. Select "**Submit a Solution Summary**" or "**Submit Full Proposal**"
3. Select the applicable ARPA-H solicitation and enter the required information (i.e., submitter info, organizations, contacts)
4. Complete submission
5. Wait for a response or feedback from ARPA-H



Home | Submit Solution Summary | Submit Full Proposal

Submit a Solution Summary

* = required field



Live Demonstration

ARPA-H Solution Submission Portal

The screenshot shows the ARPA-H SOLUTIONS website. At the top, there is a navigation bar with 'Home', 'Event Registration', and 'Sign in'. The main heading is 'ARPA-H Solution Submission Portal'. Below this, there are two buttons: 'Sign Up Today' (circled in red) and 'Already have an account? Sign In!' (with 'Sign In!' circled in red). Two red arrows point from these buttons to the right. The 'Sign Up Today' arrow points to the text 'For new users/accounts', and the 'Sign In!' arrow points to 'For existing users/accounts'. Below the buttons, there is a list of bullet points: 'Solution Summary: a concept summary document for proposers to submit to ARPA-H prior to investing resources for a full proposal submission.' and 'Full Proposal: a full application for a new or innovative idea.' In the center of the page, there is a large graphic featuring a central family photo surrounded by several circular portraits of diverse healthcare professionals, all set against a background of a stylized molecular or network structure.

For new users/accounts

For existing users/accounts

10. Helpful ISO Resources (FAQs, Lessons Learned, and Tips)

ISO FAQs

- **What is an Innovative Solutions Opening (ISO)?**

An ISO is a solicitation instrument uniquely created by ARPA-H to make awards for R&D projects (can be in the form of a Program-Specific or Mission Office ISO). ISOs are not bound by the Federal Acquisition Regulations or Federal assistance regulations.

- **What types of entities are eligible to submit to ISOs?**

Any entity capable of satisfying the government’s needs may submit to ISOs; however, there are some limitations for FFRDCs, other government entities, and non-US entities.

- **Can entities only submit one proposal to each Program-Specific ISO?**

Yes, entities (per UEI) may generally only submit one proposal to each Program-Specific ISO as the primary proposer; however, one entity may submit multiple solution summaries to each Program-Specific ISO. Separately, entities may propose within multiple teams as a teaming partner (sub-awardee).

- **Who reviews the technical merit of the solution summaries and proposals and how are reviewers selected?**

Reviewers may be ARPA-H Programs Managers or other qualified personnel from other government organizations. For each ISO, ARPA-H selects personnel deemed proficient in the pertinent research area(s). Non-government subject matter experts may be utilized to provide feedback as advisors on proposed solutions; however, they are restricted by contractual terms and non-disclosure agreements.



ISO FAQs

- **How are solution summaries and proposals evaluated?**

Solution summaries and proposals are reviewed as specified in each ISO. Solution summaries are not evaluated to the same extent as full proposals since they are only concept summary documents.

- **What is the maximum number of teams and/or people for each proposal?**

There is no maximum number of teams or people per proposal. It is the proposer's responsibility to propose a team comprised of personnel capable of meeting the proposed work.

- **Are international entities eligible to submit proposals for ARPA-H opportunities?**

Yes, international entities are allowed to submit proposals or collaborate with US entities as team members. Per 42 U.S.C. 290c, the ARPA-H Director shall prioritize awarding any contracting instruments to entities that will conduct funded work in the US and, where appropriate and practicable, encourage nondomestic recipients of contracting instruments to collaborate with domestic entities. In no case will ARPA-H evaluate proposals from or make awards to entities organized under the laws of a covered foreign country.

- **Are program metrics included in individual ISOs considered requirements and how will ARPA-H measure performance for performers?**

Program metrics included in ISOs are generally considered requirements and not subject to change. Proposers that do not propose to meet the metrics outlined in the ISO may not be selected for negotiation for award. ARPA-H will measure performance based on the agreement terms, as agreed upon by all parties of the agreement.



ISO Lessons Learned & Tips

- Visit ARPA-H's website for team members (primarily submitters) to get oriented with ARPA-H's ISO process and Solution Submission Portal
 - ISOs are not Broad Agency Announcements (BAAs) and are not used by other government entities
 - ARPA-H does not use eRA Commons for submissions
- Read the entire ISO before making a submission
- Programs are the lifeblood of ARPA-H; thus, Program-Specific ISOs are considered a higher priority than Mission Office ISOs
- Response times for ARPA-H to respond to Program-Specific and Mission Office ISO submissions will vary (resources and priorities)
- Make sure solution summaries and proposals are submitted to the correct area on ARPA-H's Solution Submission Portal
- Adhere to page limits and produce the required information outlined for each ISO and submission type (conforming)
- There is not currently a way for submitters to check submission status on ARPA-H's Solution Submission Portal (be patient for ARPA-H to respond)

ISO Lessons Learned & Tips (cont.)

- Programs ISOs are not all the same, as some have different requirements and metrics
- Submit early → submissions submitted after posted deadlines will be considered late and will not be reviewed (non-conforming)
- Not all questions can be answered promptly → it is better to submit a solution than to miss a deadline waiting for a response
- Solution summary responses are 'encourage' and 'discourage' → interested parties can still complete a proposal submission if they receive a 'discourage' response (purely at their discretion)
- For proposals, separate documents by type unless specifically asked for a bundle
- Proposers must be registered in SAM.gov (with UEI) to receive an award

Closure / Wrap-Up

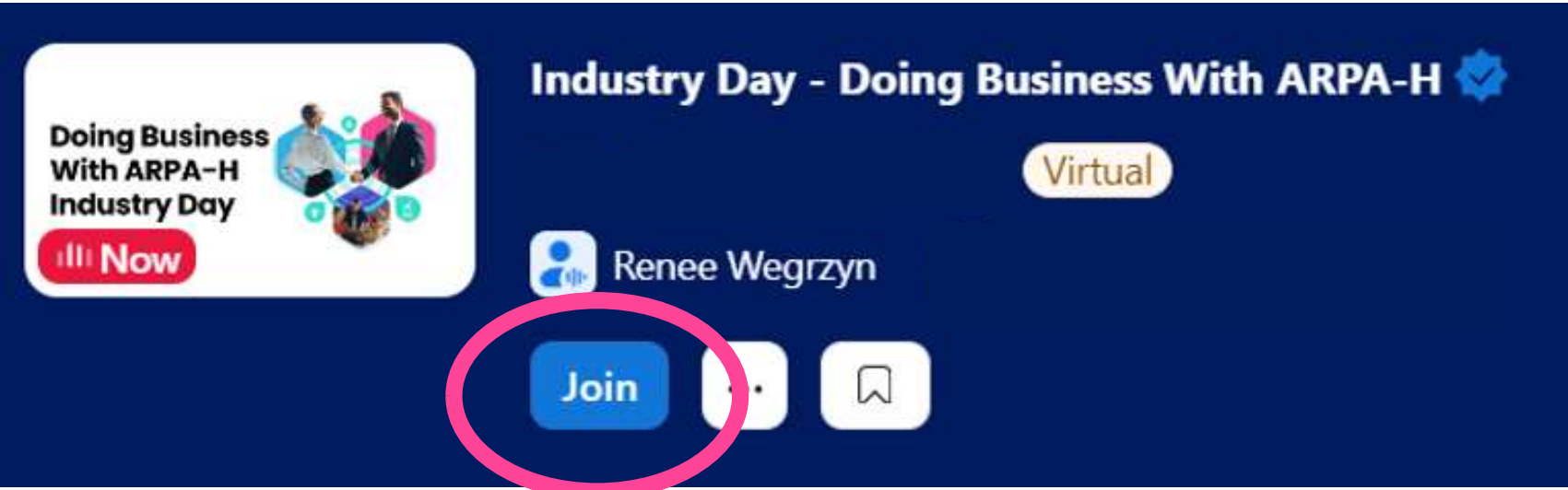
Closure / Wrap-Up

- Thank you for attending the virtual “Doing Business With ARPA-H” event
- We hope you learned more about ARPA-H’s mission, authorities, and R&D funding opportunities
- The following breakout session is our last event session
- We will **not** regroup after the breakout session
- Presentation content and Q&As will be available for viewing on ARPA-H’s public website after the event
- Email DBWA@arpa-h.gov if you have any questions about the event or would like to provide feedback
- Attendees will receive a post-event survey

11. Breakout Period 2

Logistics for Breakout Rooms

- Join one of the 10 breakout sessions offered ("Session 2")
- The breakout session period is 35 minutes
- Ask questions in the chat
- All can leave the event after breakout session



Breakout Session Topics and Descriptions

Topic #	Topic	Description
1	Work With Us Q&A	Ask questions related to doing business with ARPA-H (“Ask Us Anything”)
2	You Received an Award, Now What?	An overview of typical post-award activities associated with ARPA-H research and development (R&D) efforts
3	OT Benefits	An overview of OTs and the expected benefits of using OTs
4	Payable Milestones	An overview of ARPA-H’s preference for payable milestones on R&D efforts
5	Intellectual Property (IP) Approach	An overview of IP and ARPA-H’s approach to IP
6	Teaming	An overview of teaming opportunities within specific ARPA-H programs and the importance of teaming with small business and Minority Serving Institutions (MSIs)
7	Affordability and Accessibility	An overview of affordability and accessibility and the importance to ARPA-H’s mission
8	International Collaboration	A session on opportunities for international collaboration, for both domestic and foreign proposers
9	Accelerating Program Transition	An overview of PATIO and the goal to transition health research innovations into solutions that reach everyone
10	Engaging with FFRDCs and GEs	Learn how ARPA-H can collaborate with and government entities

**This concludes the event.
Thank you for attending!**

Questions or feedback?

Email:

DBWA@arpa-h.gov

ARPA 